DOCKET NO.: MPCI-0033
Application No.: 09/928,467
Office Action Dated: April 25, 2003

PATENT
REPLY FILED UNDER EXPEDITED PROCEDURE PURSUANT TO 37 CFR § 1.116

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

Please cancel claims 1-81 and add claims 82-105 as follows:

1-81. **(Canceled)**

82. (New) A stable pharmaceutical formulation comprising:

a non-aqueous granulate comprising:

at least one cyclic amino acid which is susceptible to formation of a lactam;

at least 20 ppm of an anion of a mineral acid, based on the weight of said at least one cyclic amino acid; and

at least one stabilizer to inhibit the formation of said lactam,

wherein said formulation contains less than 2% by weight of a degradation product of the amino acid after being maintained for 3 months at 40 degrees Centigrade and 75 % relative humidity.

83. (New) The formulation of claim 82 wherein said stabilizer is ethanol, acetone, glycerin, propylene glycol, or polysorbates.

84. (New) The formulation of claim 82 wherein said stabilizer is ethanol.

85. (New) The formulation of claim 82 wherein said cyclic amino acid is gabapentin.

86. (New) The formulation of claim 82 wherein the anion of a mineral acid is chloride ions.

87. (New) The formulation of claim 82 wherein said non-aqueous granulate is prepared by dispersing said at least one cyclic amino acid in said at least one stabilizer;

contacting a mineral acid with said at least one stabilizer and said at least one cyclic amino acid in an amount sufficient to provide at least 20 ppm anion of a mineral acid, based on the weight of said at least one amino acid; and

substantially completely removing said at least one stabilizer.

88. (New) The formulation of claim 82 wherein said formulation is a unit dosage form.

89. (New) The formulation of claim 82 wherein said at least one cyclic amino acid is susceptible to formation of a lactam via a dehydration reaction that causes cyclization of said at least one amino acid to a lactam.

90. (New) The formulation of claim 82 wherein said formulation after said removing step contains no more than 0.5% by weight of lactam after being maintained for 3 months at 40 degrees Centigrade and 75% relative humidity.

91. (New) The formulation of claim 82 wherein said formulation after said removing step contains no more than 0.7% by weight of lactam after being maintained for 20 days at 60 degrees Centigrade and 75% relative humidity.

92. (New) A method of removing lactam from a cyclic amino acid comprising the steps of:

dispersing said amino acid in a non-aqueous granulating liquid;

contacting said non-aqueous granulating liquid with a mineral acid in an amount sufficient to provide more than 20 ppm of anion of said mineral acid, based on the weight of said cyclic amino acid; and

substantially completely removing said non-aqueous granulating liquid.

93. (New) The method of claim 92 wherein said formulation after said removing step contains less than 2% by weight of lactam after being maintained for 3 months at 60 degrees Centigrade and 75 % relative humidity.

94. (New) The formulation of claim 92 wherein said formulation after said removing step contains no more than 0.5% by weight of lactam after being maintained for 3 months at 40 degrees Centigrade and 75% relative humidity.

95. (New) The formulation of claim 92 wherein said formulation after said removing step contains no more than 0.7% by weight of lactam after being maintained for 20 days at 40 degrees Centigrade and 75% relative humidity.

96. (New) A stable pharmaceutical formulation comprising:

(i) an active agent consisting essentially of

gabapentin in the free amino acid, crystalline anhydrous form;

less than 0.5% by weight of its corresponding lactam; and

greater than 20 ppm of an anion of a mineral acid;

(ii) at least one stabilizer to inhibit formation of said lactam; and

(iii) one or more pharmaceutically acceptable adjuvants;

wherein said formulation contains less than 2% by weight of a degradation product of the amino acid after being maintained for 3 months at 40 degrees Centigrade and 75 % relative humidity.

97. (New) The formulation of claim 96 wherein said stabilizer is ethanol, acetone, glycerin, propylene glycol, or polysorbates.

98. (New) The formulation of claim 96 wherein said stabilizer is ethanol.

99. (New) The formulation of claim 96 wherein said anion of a mineral acid is chloride ions.

100. (New) The formulation of claim 96 wherein said active agent is prepared by dispersing said gabapentin in said at least one stabilizer;

contacting said mineral acid with said at least one stabilizer and said gabapentin in an amount sufficient to provide more than 20 ppm anion of a mineral acid, based on the weight of said gabapentin; and

substantially completely removing said at least one stabilizer.

101. (New) The formulation of claim 96 wherein said formulation is a unit dosage form.

102. (New) The formulation of claim 96 wherein said gabapentin is susceptible to formation of a lactam via a dehydration reaction that causes cyclization of said at least one amino acid to a lactam.

103. (New) The formulation of claim 96 wherein said formulation after said removing step contains no more than 0.5% by weight of lactam after being maintained for 3 months at 40 degrees Centigrade and 75% relative humidity.

104. (New) The formulation of claim 96 wherein said formulation after said removing step contains no more than 0.7% by weight of lactam after being maintained for 20 days at 60 degrees Centigrade and 75% relative humidity.

105. (New) The formulation of claim 96 wherein substantially completely removed is at least about 90% by weight.